

## SPECIALTY GUIDELINE MANAGEMENT

### BRUKINSA (zanubrutinib)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indication

Brukina is a kinase inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

All other indications are considered experimental/investigational and not medically necessary.

##### II. CRITERIA FOR INITIAL APPROVAL

##### **Mantle Cell Lymphoma**

Authorization of 12 months may be granted for treatment of mantle cell lymphoma when the member has received at least one prior therapy.

##### III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

##### IV. REFERENCES

1. Brukina [package insert]. San Mateo, CA: BeiGene USA, Inc.; November 2019.